# TRAITÉ DE COOPÉRATION EN MATIÈRE DE BREVETS

# PCT

## RAPPORT PRÉLIMINAIRE INTERNATIONAL SUR LA BREVETABILITÉ

(chapitre I du Traité de coopération en matière de brevets)

(règle 44*bis* du PCT)

| | | |
|---|---|---|
| Référence du dossier du déposant ou du mandataire<br>B1506WO | **POUR SUITE À DONNER** Voir le point 4 ci-dessous | |
| Demande internationale no.<br>PCT/FR2005/001528 | Date du dépôt international *(jour/mois/année)*<br>17 June 2005 (17.06.2005) | Date de priorité *(jour/mois/année)*<br>17 June 2004 (17.06.2004) |
| Classification internationale des brevets (8$^{e}$edition, sauf indication d'une #dition ant#rieure)<br>Voir les informations pertinentes dans le formulaire PCT/ISA/237 | | |
| Déposant<br>SIDEM PHARMA S.A. | | |

1. Le présent rapport préliminaire international sur la brevetabilité (chapitre I) est établi par le Bureau international au nom de l'administration chargée de la recherche internationale selon la règle 44*bis*.1.a).

2. Ce RAPPORT comprend un total de 8 feuilles, y compris la présente feuille de couverture.

   Dans les feuilles jointes, toute référence à l'opinion écrite de l'administration chargée de la recherche internationale doit être entendue, à la place, comme une référence au rapport préliminaire international sur la brevetabilité (chapitre I).

3. Le présent rapport contient des indications relatives aux points suivants :

| | | |
|---|---|---|
| ☒ | Cadre n° I | Base de l'opinion |
| ☐ | Cadre n° II | Priorité |
| ☒ | Cadre n° III | Absence de formulation d'opinion quant à la nouveauté, l'activité inventive et la possibilité d'application industrielle |
| ☐ | Cadre n° IV | Absence d'unité de l'invention |
| ☒ | Cadre n° V | Déclaration motivée selon l'article 35.2) quant à la nouveauté, l'activité inventive et la possibilité d'application industrielle; citations et explications à l'appui de cette déclaration |
| ☒ | Cadre n° VI | Certains documents cités |
| ☐ | Cadre n° VII | Certaines irrégularités relevées dans la demande internationale |
| ☐ | Cadre n° VIII | Certaines observations relatives à la demande internationale |

4. Le Bureau international communiquera le présent rapport aux offices désignés conformément aux règles 44*bis*.3.c) et 93*bis*.1 mais pas avant l'expiration du délai de 30 mois à compter de la date de priorité (règle 44*bis*.2), sauf si le déposant a présenté une requête expresse à cet égard en vertu de l'article 23.2).

| | |
|---|---|
| | Date d'établissement du présent rapport<br>28 December 2006 (28.12.2006) |
| Bureau international de l'OMPI<br>34, chemin des Colombettes<br>1211 Geneva 20, Switzerland<br>no de télécopieur +41 22 338 82 70 | Fonctionnaire autorisé<br>Beate Giffo-Schmitt<br>e-mail: pt03@wipo.int |

# PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

# PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

| | |
|---|---|
| Date of mailing *(day/month/year)* | See form PCT/ISA/210 |
| Applicant's or agent's file reference<br>B1506WO | FOR FURTHER ACTION<br>See paragraph 2 below |

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/FR2005/001528 | 17.06.2005 | 17.06.2004 |

International Patent Classification (IPC) or both national classification and IPC
C07D471/04, A61K31/437, A61P1/04

Applicant
SIDEM PHARMA

1. This opinion contains indications relating to the following items:

| | | |
|---|---|---|
| ☒ | Box No. I | Basis of the opinion |
| ☐ | Box No. II | Priority |
| ☒ | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| ☐ | Box No. IV | Lack of unity of invention |
| ☒ | Box No. V | Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| ☒ | Box No. VI | Certain documents cited |
| ☐ | Box No. VII | Certain defects in the international application |
| ☐ | Box No. VIII | Certain observations on the international application |

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

| | |
|---|---|
| Name and mailing address of the ISA/EP<br><br>Facsimile No. | Authorized officer<br><br>Telephone No. |

**WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/FR2005/001528

**Box No. I Basis of this opinion**

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in the international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/FR2005/001528

**Box No. III** **Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 7 "industrial application"

because:

☒ the said international application, or the said claims Nos. 7
relate to the following subject matter which does not require an international preliminary examination (*specify*):

The present Authority considers that the subject matter of claim 7 is covered by the provisions of PCT Rule 67.1(iv). For this reason, no opinion will be given on the question of whether the subject matter of this claim is industrially applicable (PCT Article 34(4)(a)(i)).

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

**WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/FR2005/001528

**Box No. V** **Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Claims | 1-19 | YES |
| | Claims | | NO |
| Inventive step (IS) | Claims | | YES |
| | Claims | 1-19 | NO |
| Industrial applicability (IA) | Claims | 1-6, 8-19 | YES |
| | Claims | | NO |

2. Citations and explanations:

Reference is made to the following documents:

D1: EP 0 254 588 A1 (TOKYO TANABE COMPANY LIMITED) 27 January 1988

D2: KAKINOKI B ET AL: "General pharmacological properties of the New Proton Pump Inhibitor (+-)-5-Methoxy-2-ÄÄ(4-methoxy-3,5-dimethylpyrid-2-yl)methylÜsulfinyl Ü-1H-imidazo Ä4,5-bÜpyridine" METHODS AND FINDINGS IN EXPERIMENTAL AND CLINICAL PHARMACOLOGY, PROUS, BARCELONA, ES, vol. 21, no. 3, 1999, pages 179-187.

The present application relates to an S-tenatoprazole sodium monohydrate salt that is considered to be of use as an inhibitor of gastric acid secretion. Documents D1 and D2 do not disclose such a sodium salt; therefore, novelty is recognized for claims 1-19 (PCT Article 33(2)).

Documents D1 and D2 do not contain an indication for a sodium salt of the S enantiomer of tenatoprazole. An inventive step could therefore be recognized. However, the description does not demonstrate advantages linked to the sodium salt of said enantiomer. For this reason, the subject matter of claims 1-19 does not involve an inventive step as defined in PCT Article 33(3).

For the assessment of the present claim 7 on the question of whether it is industrially applicable, no unified criteria exist in the PCT Contracting States. Patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject matter of claims relating to the use of a compound in a medical treatment, but may allow,

**Box No. V** **Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

however, claims relating to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

**WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/FR2005/001528

**Box No. VI Certain documents cited**

1. Certain published documents (Rule 43*bis*.1 and 70.10)

| Application No. Patent No. | Publication date (day/*month/year*) | Filing date (day/*month/year*) | Priority date (valid claim) (*day*/month/*year*) |
|---|---|---|---|

see supplemental sheet

2. Non-written disclosures (Rule 43*bis*.1 and 70.9)

| Kind of non-written disclosure | Date of non-written disclosure (day/*month/year*) | Date of written disclosure referring to non-written disclosure (*day*/month/*year*) |
|---|---|---|

see form 210

**WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/FR2005/001528

**Supplemental Box**

**In case the space in any of the preceding boxes is not sufficient.**

Continuation of:

Box VI

The following documents may be important in the European phase:

D1: FR-A1-2 848 555 (NEGMA GILD) 18 June 2004 (2004-06-18)

D2: WO 2004/074285 A1 (MITSUBISHI PHARMA CORPORATION; YAMASHITA, SETSUO; EBINA, KENGO) 2 September 2004 (2004-09-02)